JUL 1 4 2000

K990165

510(k) Summary

Submitted By: Biopro
17 17th Street
Port Huron, MI 48060
Contact: Cheryl Warsinske
Tel (810) 982-7777
Fax (810) 982-7794

Device Information:
Proprietary name: Biopro Tara Poly Insert
Common name: Hip joint, metal/polymer semi-constrained, resurfacing, cemented prosthesis
Classification name: Hip joint, metal/polymer semi-constrained, resurfacing, cemented prosthesis

Biopro Tara Poly Insert
The Biopro Tara Poly Insert is manufactured from UHMWPE. It is designed to snap-fit into the Biopro Cox Comb Cup (510K#K882869) and articulate with the Biopro ceramic or cobalt chrome Tara component (510K#'s K962514 and K894604). The insert is available in 17 sizes ranging from 38x53mm to 55x69mm. The Biopro Tara Poly Insert has been designed for use with the ceramic tara femoral component in appropriately indicated patients with severe pain and disability associated with advanced coxarthrosis that may be due to rheumatoid, post-traumatic, or degenerative arthritis. The proposed prosthesis is substantially equivalent to the THARIES low profile metal-backed socket. The predominant design features include:
1) Accommodations for a 38,41,43,45,47,49,51,53, and 55 Tara femoral component.
2) The tara insert allows for a stable joint while allowing a very good range of motion. Side cuts are designed into the cup and insert to allow the increased ROM. The contact area between the head and the insert is not comprimised as a result of the cutouts because the cut-out design leaves sufficient material superiorly. Having "extra" material in areas in which dislocation most often occurs, lowers the risk of dislocation happening.
3) A locking groove that securely locks the insert into the acetabular shell. Push-out force ranged from 150 pounds to 230 pounds.

Substantial Equivalence: The Biopro Tara Poly Insert is substantially equivalent to the THARIES low profile metal-backed socket. The tara insert is available in sizes ranging from 38x53mm to 55x69mm, while the THARIES insert is available in sizes ranging from 36x53mm to 51x69mm. Both inserts are manufactured of UHMWPE to ASTM F648. Both inserts are designed to fit into a metal-backed shell, and both inserts mate with resurfacing head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2000

Cheryl L. Warsinske, M.S.
Director of Engineering
Biopro
17 17th Street
Port Huron, Michigan 48060

Re: K990165
Trade Name: Biopro Tara Poly Insert
Regulatory Class: III
Product Code: KXB
Dated: March 15, 1999
Received: March 22, 1999

Dear Ms. Warsinske:

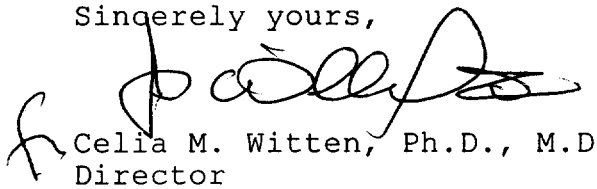
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510k Number (if known): K990165

Device Name: Biopro Tara Poly Insert

Indications for Use:

A) Osteoarthritis
B) Rheumatoid arthritis with severe hip pain and limited joint motion
C) Avascular necrosis
D) Traumatic arthritis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990165

Prescription Use---X---
(Per 21 CFR 801.109)

OR

Over The Counter Use------
(Optional Format 1-2-96)